AMENDMENT TO THE SPECIFICATION

In the Specification:

Please delete the title on line 1 of page 1 and line 1 of page 21 of the specification and replace it with the replacement title set forth below, which is marked to show the changes being made.

~~FLUID DELIVERY~~ PUMPING DEVICE, SYSTEM AND METHOD EMPLOYING A SHAPE MEMORY ALLOY

Please delete line 2 of page 1 of the specification and replace it with the replacement text set forth below, which is marked to show the changes being made.

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Please delete paragraph [0001] on page 1 of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0001] This non-provisional application is related to and claims priority based on U.S. Provisional Application No. 60/417,464, entitled "Disposable Pump For Drug Delivery System," filed on October 9, 2002, and U.S. Provisional Application No. 60/424,613, entitled "Disposable Pump And Actuation Circuit For Drug Delivery System," filed on November 6, 2002, ~~and U.S. Provisional Application No. 60/424,414, entitled "Automatic Biological Analyte Testing Meter With Integrated Lancing Device And Methods Of Use," filed November 6, 2002,~~ each of which is incorporated herein in its entirety by this reference. This non-provisional application is also related to U.S. Provisional Application No. 60/424,414, entitled "Automatic Biological Analyte Testing Meter With Integrated Lancing Device And Methods Of Use," filed November 6, 2002, and U.S. Patent No. 6,560,471, entitled "Analyte Monitoring Device and Methods of Use," issued May 6, 2003, each of which is incorporated herein in its entirety by this reference.

Please delete paragraph [0008] on pages 3-4 of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0008] The device of the present invention is intended to be operated in a periodic dosing manner, i.e., liquid is delivered in periodic discrete doses of a small fixed volume rather than in a continuous flow manner. The overall liquid delivery rate for the device is controlled and adjusted by controlling and adjusting the dosing period. Thus the device employs a precision timing mechanism in conjunction with a relatively simple mechanical system, as opposed to a complex mechanical system, such as that embodied by the syringe pump. A precision timing device is an inherently small, simple and inexpensive device. It is an underlying assumption of the invention (and a reasonable conclusion of process control theory) that in the treatment of diabetes, there is no clinical difference between administering insulin in periodic discrete small doses and administering insulin in a continuous flow, as long as the administration period of the discrete dose is small compared to the interval of time between which the blood glucose level is measured. For the present invention, a small dose size is regarded as on the order of 0.10 units of insulin (1 microliter) assuming a standard pharmaceutical insulin preparation of 100 units of insulin per ml (U100). A typical insulin dependent diabetic person uses between 10 and 100 units of insulin per day, with the average diabetic person using 40 units of insulin. Thus the present invention would deliver the daily insulin requirements of the average diabetic person in 400 individual discrete doses of 1 μl each with a dosing period that can be programmed by the user. A pump constructed according to the present invention can have a predetermined discrete dosage volume that is larger or smaller than 1 μl, but preferably falls within the range of 0.5 to 5 μl, and more preferably falls within the range of 1 to 3 μl. The smaller the discrete dose is of a particular pump design, the more energy required by the device to deliver a given amount of fluid, since each pump cycle consumes roughly the same amount of energy regardless of discrete dosage size. On the other hand, the larger the discrete dosage is, the less precisely the pump can mimic the human

body in providing a smooth delivery rate. A device constructed according to the present invention is also suitable for delivery of other drugs that might be administered in a manner similar to insulin.

Please delete paragraph [0037] on page 11 of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0037] A preferred embodiment of a fluid reservoir **207** appropriate for use with the present invention is one for which the volume of the fluid reservoir diminishes concomitantly as fluid is withdrawn such that it is not necessary to replace the volume of the withdrawn fluid with air or any other substance. A preferred embodiment of a fluid reservoir **207** might comprise a cylindrical bore **220** fitted with a movable piston **221**, for example, a syringe, or a balloon constructed of a resilient material.

Please delete paragraph [0045] on pages 14-15 of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0045] A first alternative embodiment of the invention is diagrammed schematically in Figure 7 and is comprised of all of the same subcomponents and elements of the most general embodiment of the invention shown in Figure 1 with the following exceptions. In a first alternative embodiment of the invention, the displacement cavity, as well as the inlet and outlet conduit, are all comprised of a single length of small-diameter flexible and resilient tubing **701**. The tubing **701** is situated within a restraining fixture **702** secured to a rigid base **703** so as to fix the position and orientation of the tubing **701** relative to the other elements of the device. Inlet **704** and outlet **705** check valves are located within the bore of the tubing **701** such that they have a common orientation for flow direction and such that a length of empty tubing **701** exists in between the two check valves **704, 705**. The volume within the inner diameter of the tubing **701** and in between the two check valves **704, 705** comprises a displacement cavity **706**. The volume of the displacement cavity

706 is varied by compressing the resilient tubing **701** with a plunger **707** (described below) at a position midway between the two check valves **704, 705**. The volume within the inner diameter of the tubing **701** and in between the two check valves **704, 705** when the tubing **701** is uncompressed defines the maximum volume of displacement cavity **706**. The volume within the inner diameter of the tubing **701** and in between the two check valves ~~**703,**~~ **704, 705** when the tubing **701** is fully compressed defines the minimum volume of the displacement cavity ~~**705**~~ **706**.

Please delete paragraph [0047] on page 15 of the specification and replace it with the replacement paragraph set forth below, which is marked to show the changes being made.

[0047] A straight length of shape memory alloy wire **713** is situated in a position coincident with the axis of the plunger **707**. One end of the shape memory alloy wire **713** is attached to the rigid base **703** and electrically connected by connection **716** to the pulse generating circuit **714** and the electric power source **715**. The other end of the shape memory alloy wire **713** along with an electrical connection **717** to that end is attached to the shaft of the plunger **707**. The shape memory alloy wire **713** is of sufficient length and strength that when heated so as to induce phase transition and associated dimensional change it will pull the plunger **707** away from contact with the resilient tubing **701** against the opposing force of the biasing spring **713**. Much as described in relation to Figure 2A, a preferred embodiment of a fluid reservoir **719** appropriate for use with the present invention is one for which the volume of the fluid reservoir diminishes concomitantly as fluid is withdrawn such that it is not necessary to replace the volume of the withdrawn fluid with air or any other substance. A preferred embodiment of a fluid reservoir **719** might comprise a cylindrical bore **718** fitted with a movable piston **720**, for example, a syringe, or a balloon constructed of a resilient material.